[ORAL ARGUMENT NOT YET SCHEDULED]
Nos. 13-5011, 13-5015 (consolidated)

IN THE UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

ALLINA HEALTH SERVICES, *et al.*,
Plaintiffs-Appellees,

v.

KATHLEEN SEBELIUS, Secretary, United States Department of Health and Human Services,
Defendant-Appellant.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

BRIEF FOR APPELLANT KATHLEEN SEBELIUS

STUART F. DELERY
Acting Assistant Attorney General

RONALD C. MACHEN JR.
United States Attorney

ANTHONY J. STEINMEYER
(202) 514-3388
STEPHANIE R. MARCUS
(202) 514-1633
Attorneys, Appellate Staff
Civil Division, Room 7642
Department of Justice
950 Pennsylvania Ave., N.W.
Washington, D.C. 20530-0001

CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

Counsel for the Department of Justice certifies the following:

A. Parties and Amici.

Allina Health Services d/b/a Abbott Northwestern Hospital; Allina Health Services d/b/a Cambridge Medical Center; Allina Health Services d/b/a Owatonna Hospital; Allina Health Services d/b/a United Hospital; Allina Health Services d/b/a Unity Hospital; Florida Health Sciences Center, Inc. d/b/a Tampa General Hospital; Henry Ford Health System d/b/a Henry Ford Hospital; Henry Ford Health System d/b/a Henry Ford Macomb Hospital; Highland Hospital of Rochester; Kaleida Health; Kingsbrook Jewish Medical Center; Lutheran Hospital Center; Maimonides Medical Center; Methodist Dallas Medical Center; Methodist Hospitals of Dallas d/b/a Methodist Charlton Medical Center; Montefiore Medical Center; Mount Sinai Medical Center of Florida, Inc. d/b/a Mount Sinai Medical Center; New York Hospital Medical Center of Queens; New York Methodist Hospital; New York and Presbyterian Hospital d/b/a New York Presbyterian Hospital Weill Cornell Medical Center; North Carolina Baptist Hospital; North Shore Long Island Jewish Health System, Inc. d/b/a Forest Hills Hospital; North Shore Long Island Jewish Health System, Inc. d/b/a Franklin Hospital; North Shore Long Island Jewish Health System, Inc. d/b/a Long Island Jewish Medical Center; North Shore Long Island Jewish Health System, Inc. d/b/a North Shore University Hospital; North Shore Long Island Jewish Health System, Inc.

d/b/a Southside Hospital; North Shore Long Island Jewish Health System, Inc. d/b/a Staten Island University Hospital; Shands Medical Center, Inc. d/b/a Shands Jacksonville; Shands Teaching Hospital and Clinics, Inc. d/b/a Shands Hospital at the University of Florida; and University of Rochester d/b/a Strong Memorial Hospital of the University of Rochester were plaintiffs before the district court and appear as appellees before this Court.

Kathleen Sebelius, in her official capacity as Secretary of the United States Department of Health and Human Services, was the defendant before the district court and appears as appellant before this Court.

No intervenors or amici appeared in the district court proceedings.

B. Rulings Under Review.

The rulings under review are (1) the November 15, 2012 Order and memorandum opinion of the district court (Collyer, J.), in *Allina Health Servs.* v. *Sebelius*, D.D.C. No. 10-1463, which is reported at 904 F. Supp.2d 75 (D.D.C. 2012), and (2) the November 16, 2012 Order of the district court (Collyer, J.) in *Florida Health Sciences Ctr., Inc.* v. *Sebelius*; D.D.C. No. 12-328.

C. Related Cases.

These consolidated cases have not previously been before this Court. The following appeals involve the same defendant and related (but not the same) legal issues and are currently pending in this Court: *Catholic Health Initiatives* v. *Sebelius*, D.C. Cir. No.

12-5092, opinion issued June 11, 2013 (mandate not yet issued) – F.3d --, 2013 WL 2476896 (D.C. Cir. 2013), and *Columbia St. Mary's Hosp., Milwaukee, Inc.* v. *Sebelius*, D.C. Cir. No. 12-5378 (in abeyance). There are also cases involving the same defendant and related (but not the same) legal issues pending in the United States District Court for the District of Columbia: (1) *Alegent Health - Bergan Mercy Health Syst.* v. *Sebelius*, (D.D.C. No. 10-1354) (ESH); (2) *Beth Israel Deaconess Med. Ctr.* v. *Sebelius*, (D.D.C. No. 10-1593) (ESH); (3) *Adcare Hosp. of Worcester, Inc.* v. *Sebelius*, (D.D.C. No. 10-2009) (ESH); (4) *Miriam Hosp.* v. *Sebelius*, (D.D.C. No. 11-0704)(ESH); (5) *Healthalliance Hosp., Inc.* v. *Sebelius*, (D.D.C. No. 11-0705) (ESH); (6) *Bay Area Healthcare Group, Ltd.* v. *Sebelius*, (D.D.C. No. 11-1958) (ESH); (7) *Baptist Memorial Hosp. -DeSoto, Inc.* v. *Sebelius*, (D.D.C. No. 11-2278) (ESH); (8) *Saint Elizabeth Regional Med. Ctr.* v. *Sebelius*, (D.D.C. No. 12-0458) (ESH); (9) *Baptist St. Anthony's Health Syst.* v. *Sebelius*, (D.D.C. No. 12-1366) (ESH); (10) *Empire Health Foundation* v. *Sebelius*, (D.D.C. No. 11-1723) (JEB).

Respectfully submitted,

/s/ Stephanie R. Marcus
Anthony J. Steinmeyer (202) 514-3388
Stephanie R. Marcus (202) 514-1633
Department of Justice
Civil Division, Appellate Staff
950 Pennsylvania Ave., N.W. Room 7642
Washington, DC 20530-0001

TABLE OF CONTENTS

Page

Cases:

---

* Authorities chiefly relied upon are marked with an asterisk.

Statutes:

Rules:

Regulations:

GLOSSARY

"BBA"	Balanced Budget Act of 1997
"Board"	Provider Reimbursement Review Board
"CMS"	Centers for Medicare & Medicaid Services
"DSH"	Disproportionate share hospital
"EJR"	Expedited judicial review
"FY"	Fiscal year
"HHS"	United States Department of Health and Human Services
"HMO"	Health maintenance organization
"NPR"	Notice of program reimbursement
"NPRM"	Notice of proposed rulemaking
"PRRB"	Provider Reimbursement Review Board
"Secretary"	Secretary of Health and Human Services
"SSI"	Supplemental security income

STATEMENT OF SUBJECT MATTER AND APPELLATE JURISDICTION

Plaintiffs' complaints invoked the district court's jurisdiction under 42 U.S.C. § 1395oo(f)(1). RA1 at ¶6, JA -; RFH1 at ¶4, JA -.[1] On November 15, 2012, the district court issued a final order entering judgment for plaintiffs in *Allina Health Servs.* v. *Sebelius* (No. 13-5011) (*Allina*).[2] RA44, JA -. On November 16, 2012, the district court issued a final order entering judgment for plaintiffs in *Florida Health Sciences Ctr., Inc.* v. *Sebelius* (No. 13-5015) (*Florida Health Sciences*). RFH10, JA -. Defendant filed a timely motion to amend the judgment under Fed. R. Civ. P. 59(e) in *Allina*, which the district court denied on December 18, 2012. RA45, RA47, JA -. Defendant filed timely notices of appeal in both *Allina* and *Florida Health Sciences* on January 11, 2013. RA48; RFH11. This Court has jurisdiction over the consolidated appeals under 28 U.S.C. § 1291.

---

[1] "RA" refers to the Record on Appeal in *Allina Health Servs.* v. *Sebelius* (No. 05-5011); "RFH" refers to the Record on Appeal in *Florida Health Sciences Ctr., Inc.* v. *Sebelius* (No. 05-5015). Citations to the record include the page or paragraph number therein, in the following form: "RA or RFH [docket number] at --." When a document is designated for the Joint Appendix, an additional cite will appear as follows: "JA -."

[2] The district court's final order in *Allina* also encompassed *Florida Health Sciences Ctr., Inc.* v. *Sebelius* (D.D.C. No. 10-1462), which the court consolidated with *Allina* and closed upon consolidation, such that any additional documents in that case were filed in *Allina* only. RA10. Thus, references to *Allina* also include that case. The government separately filed a notice of appeal in a later district court case, *Florida Health Sciences Ctr., Inc.* v. *Sebelius*, (D.D.C. No. 12-328), which became D.C. Cir. No. 13-5015, and is consolidated with *Allina* on appeal.

STATEMENT OF THE ISSUES PRESENTED FOR REVIEW

In these consolidated cases, plaintiff hospitals challenge the calculation of their fiscal year (FY) 2007 disproportionate share hospital (DSH) adjustment under the Medicare statute. Specifically, these appeals involve the Secretary of Health and Human Services's (Secretary) treatment of the patient days of individuals enrolled in Medicare Part C for purposes of calculating plaintiffs' Medicare DSH adjustments. The questions presented are:

1. Whether the district court erred by holding that the portion of the Secretary's 2004 final rule in which the agency decided to include patient days of Medicare Part C enrollees in the Medicare/Supplemental Security Income (SSI) fraction of the DSH calculation violated the notice requirement of the Administrative Procedure Act (APA).

2. Whether the district court erred by holding that in the 2004 final rule, the Secretary failed to provide a reasoned explanation for her decision to include Medicare Part C days in the Medicare/SSI fraction of the DSH calculation.

3. Whether the district court erred by vacating the portion of the Secretary's 2004 final rule that addressed the treatment of Medicare Part C days in the DSH calculation and by prohibiting the Secretary from applying her interpretation to plaintiffs' FY 2007 DSH adjustments.

STATUTES AND REGULATIONS INVOLVED

Relevant statutory and regulatory provisions are attached in the addendum.

STATEMENT OF THE CASE

1. These consolidated appeals involve the calculation of Medicare payments to hospitals that serve significantly disproportionate numbers of low-income patients. Such hospitals may receive an additional payment, known as a "disproportionate share hospital" or "DSH" adjustment. To calculate a hospital's DSH adjustment, the Secretary determines: (1) the percentage of the hospital's patient days attributable to patients "entitled to benefits under [Medicare] part A" that are also attributable to patients who are entitled to SSI benefits – known as the "Medicare/SSI fraction"; and (2) the percentage of total patient days that are attributable to patients who are "eligible for [Medicaid] but *not* "entitled to benefits under [Medicare] part A" – known as the "Medicaid fraction." 42 U.S.C. § 1395ww(d)(5)(F)(vi)(I), (II).

The specific issue here is whether patient days attributable to individuals enrolled in Medicare Part C (who receive their Medicare benefits through managed care organizations) should be included in the Medicare/SSI fraction. Under the Secretary's interpretation, Medicare Part C enrollees remain "entitled to benefits under part A" because they continue to meet the statutory criteria for entitlement to Medicare Part A benefits. Indeed, to enroll in Part C, a beneficiary must be "entitled to benefits under part A." 42 U.S.C. § 1395w-21(a)(3)(A). Accordingly, the Secretary

included Medicare Part C patient days in plaintiff hospitals' FY 2007 Medicare/SSI fractions.

Plaintiffs in the present appeals contended that the plain language of the Medicare statute precluded the Secretary's interpretation, and that the agency violated APA rulemaking requirements in its 2004 final rule when it determined that Medicare Part C days should be included in the Medicare/SSI fraction. Prior to the district court's decision, this Court rejected plaintiffs' statutory interpretation argument in an earlier action filed by another hospital. *Northeast Hosp. Corp.* v. *Sebelius*, 657 F.3d 1, 6-13, 17 (D.C. Cir. 2011). In *Northeast*, the Court held that the plain language of the Medicare statute did not foreclose the Secretary's interpretation at *Chevron* step 1. *Id.* The Court did not reach whether the Secretary's interpretation was reasonable at *Chevron* step 2 because it held that the Secretary had an established practice, prior to the 2004 rulemaking, of excluding Medicare Part C days from the Medicare/SSI fraction, and could not apply her current interpretation retroactively to the fiscal years that predated the rulemaking. *Id.* at 14-17. The Court did not cite any evidence that Part C days were included in the Medicaid fraction numerator, however. See *id.* The present appeals involve FY 2007, which, unlike the FYs at issue in *Northeast*, postdates the Secretary's 2004 notice-and-comment rulemaking that announced her policy of including Medicare Part C patient days in the Medicare/SSI fraction.

2. The district court (Collyer, J.) granted summary judgment in favor of plaintiffs in *Allina*. Nov. 15, 2012 Opinion, RA43 ("Op.") at 32, JA -. The court held that it was unnecessary to reach plaintiffs' statutory interpretation arguments because the Secretary had committed procedural violations of the APA that required vacatur of the portion of the 2004 final rule that addressed Medicare Part C patient days. Op. 18, JA -. The court held that the Secretary violated the APA's notice requirement because in the 2003 Notice of Proposed Rulemaking (NPRM), she had proposed excluding Part C days from the Medicare/SSI fraction, but in the 2004 final rule, she adopted the opposite policy of *including* such days. Op. 22-23, JA -. The court also held that the Secretary failed to adequately explain her decision in the 2004 final rule. Op. 28-31, JA -. The court vacated the portion of the 2004 final rule that addressed the treatment of Part C days in the DSH calculation and held that the Secretary "cannot impose her new interpretation on the FY 2007 calculations challenged in this case." Op. 32, JA -. On November 16, 2012, the court issued an order in *Florida Health* granting summary judgment to plaintiffs because its "resolution of *Allina* * * * is dispositive of the issues presented in this case." RFH10, JA -.

The government filed a motion pursuant to Fed. R. Civ. P. 59(e), seeking clarification that the court's judgment applied solely to the plaintiffs and fiscal year at issue. RA45. On December 18, 2012, the court denied the motion on the ground that clarification was unnecessary since no other parties besides plaintiffs and no other

fiscal years other than FY2007 were before the court. RA47, JA -. The Secretary filed timely notices of appeal in both *Allina* and *Florida Health* on January 11, 2013. RA48; RFH11. On February 14, 2013, this Court consolidated the appeals in *Allina* and *Florida Health*. See Feb. 14, 2013 Order.

STATEMENT OF FACTS

A. Statutory And Regulatory Framework.

1. Medicare DSH Adjustment.

The Medicare program, Title XVIII of the Social Security Act, 42 U.S.C. § 1395 *et seq.*, provides health insurance coverage to individuals who are at least 65 years old and are entitled to monthly Social Security benefits, and to disabled individuals who meet specified eligibility requirements. 42 U.S.C. § 426(a), (b). Those persons are automatically entitled to benefits under Medicare Part A, which authorizes payments for covered inpatient hospital, home health and hospice treatment and related services. 42 U.S.C. § 426(a) ("Every individual who * * * has attained age 65, and is entitled to [monthly Social Security benefits] * * * shall be entitled to hospital benefits under part A."). The Secretary administers the program through the Centers for Medicare & Medicaid Services (CMS).

Hospitals that "serve[] a significantly disproportionate number of low-income patients" are entitled to additional reimbursement, known as a "disproportionate share hospital" or "DSH" adjustment. 42 U.S.C. § 1395ww(d)(5)(F)(i)(I). Whether a

hospital qualifies for the Medicare DSH adjustment and the amounts of any adjustment depend on the hospital's "disproportionate patient percentage." See 42 U.S.C. § 1395ww(d)(5)(F)(v). As defined by statute, the "disproportionate patient percentage" is calculated by adding two fractions: (i) the Medicare/SSI fraction, and (ii) the Medicaid fraction. 42 U.S.C. § 1395ww(d)(5)(F)(vi)(I) & (II). The Medicare/SSI fraction is a proxy for the percentage of low-income Medicare patients. The numerator of the Medicare/SSI fraction consists of "the number of such hospital's patient days for such period which were made up of patients who (for such days) were entitled to benefits under [Medicare] part A" and "were entitled to [SSI] benefits," while the denominator consists of "patient days for such fiscal year which were made up of patients who (for such days) were entitled to benefits under [Medicare] part A." 42 U.S.C. § 1395ww(d)(5)(F)(vi)(I).

The Medicaid fraction is a proxy for low-income non-Medicare patients. The numerator consists of those patient days attributable to "patients who (for such days) were eligible" for Medicaid, but "not entitled to benefits under [Medicare] part A," and the denominator consists of total patient days. 42 U.S.C. § 1395ww(d)(5)(F)(vi)(II).

2. Medicare Part C.

From 1972 to 1998, as an alternative to the traditional fee-for-service system, Medicare beneficiaries could enroll with a managed care organization, such as a health

maintenance organization (HMO), which entered into a payment contract with Medicare. Those contracts were governed by section 1876 of the Social Security Act, 42 U.S.C. § 1395mm. Section 1876 provided for two types of contracts: (1) "cost" contracts under which a managed care organization was reimbursed for its reported costs (subject to auditing for reasonableness); and (2) "risk" contracts, under which Medicare made fixed monthly payments. 42 U.S.C. § 1395mm(a), (g), (h); 42 C.F.R. § 417.530-536; 42 C.F.R. § 417.580-598.

The Balanced Budget Act of 1997 (BBA), Pub. L. No. 105 -33, 111 Stat. 251, 426-32 (Aug. 5, 1997), provided that section 1876 risk contracts could not be renewed after January 1, 1999. See 42 U.S.C. §§ 1395mm(k)(1)(B). The BBA added a new "Part C" to the Medicare statute, also called Medicare + Choice (or M+C).[3] See 42 U.S.C. §§ 1395w-21 to 1395w-28. Part C expanded the types of private health plans through which Medicare beneficiaries may receive coverage of the Part A benefits to which they are entitled and the Part B benefits for which they have enrolled. See 42 U.S.C. §1395w-21(a)(1).

To enroll in Medicare Part C, a beneficiary must be "entitled to benefits under [Medicare] part A * * * and enrolled under [Medicare] part B." 42 U.S.C. § 1395w-

[3] The M+C program is now known as the Medicare Advantage program. See Medicare Prescription Drug, Improvement and Modernization Act of 2003, Pub. L. No. 108-173, § 201(b), 117 Stat. 2066, 2176. References herein to "Medicare Part C" patient days encompass M+C days before the change and Medicare Advantage days thereafter.

21(a)(3)(A). For Medicare beneficiaries enrolled in Part C plans, the Medicare program does not directly pay hospitals. Instead, using money from the Medicare Part A and Part B trust funds, Medicare pays the Part C plan a predetermined per-patient rate. See 42 U.S.C. § 1395w-23(f).

3. 2004 Rulemaking.

In the years following the creation of Medicare Part C, CMS began to receive questions about how Medicare Part C patient days should be treated in calculating hospitals' DSH adjustments. See 68 Fed. Reg. 27,154, 27,208 (May 19, 2003). The interpretive question at issue was whether a Medicare Part C enrollee remains "entitled to benefits under part A" within the meaning of the DSH provision. *Id.* In a May 2003 NPRM, the Secretary proposed to address "whether patients enrolled in an M+C Plan should be counted in the Medicare fraction or the Medicaid fraction of the DSH patient percentage calculation." *Id.* The Secretary "propos[ed] to clarify that once a beneficiary elects Medicare Part C, those patient days attributable to the beneficiary should not be included in the Medicare fraction of the DSH patient percentage," but instead should be included in the numerator of the Medicaid fraction if they are eligible for Medicaid *Id.*

CMS received numerous comments, including several addressing the Medicare Part C proposal. Some hospitals opposed the proposed "change," recommending instead that Medicare Part C days "continue to be counted as Medicare days" in the

DSH percentage because Medicare Part C enrollees remain entitled to part A benefits. See Administrative Record of Rulemaking, RA31 (ARR) at 327-28, 343 (N. Shore Univ. Hosp. at Plainview), JA -; 356, 370-71, JA - (Ass'n of Am. Med. Colleges); 403, 412-13, JA - (NYU Med. Ctr.); 451-52, 466, JA - (Greater NY Hosp. Ass'n); 555-56, 571, JA - (Franklin Hosp.); 575-76, 591, JA - (N. Shore Univ. Hosp. at Syosset). North Shore University Hospital and Franklin Hospital, which are part of the North Shore Long Island Jewish Health System, are plaintiffs in this case. RA1, JA -. In contrast, a few commenters recommended that Medicare Part C days be included in the Medic*aid* fraction numerator if the Part C enrollees were eligible for Medicaid. See ARR 140, 144-45, 147-49 JA - (Sw. Consulting Assoc.); 389-90, JA - (Mercy Health Sys.). In the final rule, the Secretary sided with the commenters who argued that Medicare Part C days belong in the Medic*are* fraction, because M+C enrollees are "just as much Medicare beneficiaries as those beneficiaries in the traditional fee-for-service program." 69 Fed. Reg. 48,916, 49,099 (Aug. 11, 2004) (2004 final rule).

In the 2004 final rule, the agency stated that it was "revising [its] regulations" – which at the time simply parroted the ambiguous language of the statute – to specifically "include the days associated with M+C beneficiaries in the Medicare fraction of the DSH calculation." 69 Fed. Reg. at 49,099. However, the agency inadvertently failed to make that revision in the text of the regulations themselves. For that reason, the Secretary made a "technical correction" to the regulations in 2007

to expressly incorporate the interpretation announced in the 2004 rule. 72 Fed. Reg. 47,130, 47,384 (Aug. 22, 2007). See *Northeast*, 657 F.3d at 14.

4. Medicare Payment Determinations.

Hospitals submit cost reports at the end of each fiscal year to contractors, known during the relevant time period as fiscal intermediaries, which are generally private insurance companies acting on behalf of the Department of Health and Human Services (HHS). See 42 C.F.R. §§ 405.1801(b)(1), 413.24(f). CMS determines the Medicare/SSI fraction of the DSH adjustment, and provides that information to the fiscal intermediaries. 42 C.F.R. § 412.106(b)(2). The intermediary determines the total payment (including any hospital-specific adjustments) and issues a Notice of Program Reimbursement (NPR), informing the provider how much it will be paid for the fiscal year at issue. 42 C.F.R. § 405.1803.

If a provider is dissatisfied with its NPR and meets the amount-in-controversy requirement, it may appeal to the Provider Reimbursement Review Board (PRRB or Board) "if * * * [it] files a request for a hearing within 180 days after notice of the intermediary's final determination" and meets other statutory requirements. 42 U.S.C. § 1395oo(a). If a provider has not received an NPR from the intermediary "on a timely basis" after filing a cost report, the provider may appeal to the Board if it files a request for a hearing within 180 days after notice of the intermediary's final determination "would have been received" if timely. *Id.* The decision of the Board is

final unless the Secretary reverses, affirms, or modifies the decision within 60 days. 42 U.S.C. § 1395oo(f)(1). A hospital may seek judicial review of "any final decision of the Board" by filing suit in federal district court within 60 days. *Id.* If "the Board determines that it is without authority to decide" a "question of law or regulations" presented by the hospital, the Board may grant expedited judicial review (EJR), allowing the provider to proceed directly to federal district court. *Id.*

B. The Present Litigation.

1. Plaintiffs are thirty hospitals that challenged the Secretary's treatment of Medicare Part C days in the calculation of their FY 2007 DSH adjustments. In *Allina*, plaintiff hospitals filed administrative appeals to the PRRB, seeking EJR to challenge the Secretary's decision to include Part C days in the Medicare/SSI fraction in calculating their FY 2007 DSH payments. See RA31 at 12. The PRRB granted the request. *Id.* And in *Florida Health Sciences*, two additional plaintiff hospitals filed administrative appeals to the Board, seeking EJR on the same grounds. See RFH9 at 12. The Board granted that request as well. *Id.*

2. On August 27, 2010, the plaintiffs in *Allina* filed suit in district court against the Secretary challenging the inclusion of Medicare Part C days in the Medicare/SSI fraction of their FY 2007 DSH calculations. RA1, JA -. On February 29, 2012, the plaintiffs in *Florida Health Sciences* filed suit in district court raising the same issue. RFH1, JA -. The court consolidated the cases because plaintiffs presented "the

identical issue of whether the Secretary's inclusion of Medicare Part C days in the Medicare/SSI fraction in FY 2007 was proper." Op. 11 n.7, JA -.

a. The court granted plaintiffs' motion for summary judgment.[4] Based on this Court's decision in *Northeast*, *supra*, the court started from "the proposition that '[t]he Secretary's interpretation [of the DSH calculation], as set forth in the 2004 rulemaking and resulting amendment to § 412.106, contradicts' and is a 'substantive departure' from 'her former practice of excluding M+C days from the Medicare fraction.'" Op. 20, JA - (quoting *Northeast*, 657 F.3d at 17). The court held that the Secretary violated the APA's notice requirement in the 2004 final rule when she determined that Medicare Part C days should be included in the Medicare/SSI fraction. Op. 22-26, JA -. In the court's view, the Secretary's 2004 interpretation was not a 'logical outgrowth' of the 2003 NPRM. Op. 22, JA -. The court concluded that the NPRM, in which the Secretary proposed to exclude Part C days from the Medicare/SSI fraction, did not give parties sufficient notice that the Secretary was considering adopting the contrary policy of including Part C days in that fraction. Op. 22-23, JA -.

The court further rejected the Secretary's argument that regardless of whether notice was sufficient, there was no APA violation because plaintiffs could not show

[4] Prior to briefing at the summary judgment stage, the court denied plaintiffs' motion for a preliminary injunction and granted the Secretary's motion to stay proceedings pending this Court's disposition of the appeal in *Northeast*. See op. 12, JA -; RA15, RA16.

any prejudice. Op. 26, JA -. The court also held that the Secretary failed to adequately explain her decision to include Part C days in the Medicare/SSI fraction. Op. 28-31, JA -.

b. With respect to remedy, the district court determined that vacatur of the relevant portion of the 2004 final rule was appropriate. Op. 31, JA -. The court ordered that the "portion of the 2004 Final Rule * * * that announced the Secretary's interpretation of the Medicare [DSH] Fraction, as codified in 2007 * * * and as further modified in 2010, will be vacated, and the case will be remanded to the Secretary for further action consistent with this Opinion." Op. 32, JA -. The court held that the "portion of the 2004 Final Rule * * * that announced the Secretary's interpretation of the Medicare [DSH] Fraction, as codified in 2007 at 42 C.F.R. 412.106(b)(2) and as further modified in 2010, is tantamount to the retroactive rulemaking that the D.C. Circuit held impermissible in *Northeast Hospital*," and determined that "the Secretary cannot impose her new interpretations on the FY 2007 calculations challenged in this case." *Id.* (internal quotations and citation omitted).

c. The government filed a motion pursuant to Fed. R. Civ. P. 59(e), seeking clarification that the court's judgment applied solely to plaintiffs and to the fiscal year at issue. The district court denied the motion on the ground that clarification was unnecessary. RA 47, JA -. The court's order confirmed that the Secretary's interpretation was correct since "the DSH calculations for other hospitals and other

fiscal years, or even for other hospitals for Fiscal Year 2007, were not before the Court." *Id.* at 2, JA -.

SUMMARY OF ARGUMENT

1. The district court erred by holding that the Secretary failed to meet APA notice requirements. The 2003 NPRM made clear that the agency was making a binary choice: either the Part C days would be included in the Medicare/SSI fraction (and excluded from the Medicaid fraction numerator), or they would be excluded from the Medicare/SSI fraction (and included in the Medicaid fraction numerator if the Part C enrollee was eligible for Medicaid). The proposed rule expressly presented the interpretive issue: "The question stems from whether M+C enrollees are entitled to benefits under Medicare Part A since M+C plans are administered through Medicare Part C." 68 Fed. Reg. at 27,208. Regardless of the agency's prior practice, providers and other stakeholders therefore were on notice that they should submit comments to advocate for their preferred interpretation. It makes no difference for purposes of the APA notice requirement that the agency's proposed interpretation was the opposite of the interpretation ultimately adopted in the 2004 final rule. These opposite interpretations – *i.e.*, the inclusion or exclusion of the Part C days from the Medicare/SSI fraction – were the only possible outcomes of the rulemaking.

Indeed, the comments submitted by providers demonstrate that the 2003 NPRM met APA notice requirements. The agency received comments from several

hospitals and hospital associations – including two plaintiffs in this case – opposing its proposal to exclude Part C days from the Medicare/SSI fraction. In addition, the agency received comments in favor of its proposal. These comments demonstrate that providers plainly understood the two possible outcomes of the rulemaking.

2. The comments also support the Secretary's argument that even assuming *arguendo* that the 2003 NPRM did not meet APA notice requirements, any violation would be harmless error. Under the APA, it is plaintiffs' burden to show that "the agency's violation of the APA's notice and comment procedures has resulted in 'prejudice.'" *American Coke & Coal Chem. Inst.* v. *EPA*, 452 F.3d 930, 939 (D.C. Cir. 2006) (quoting 5 U.S.C. § 706(2)). Here, plaintiffs have not shown – nor could they – that had the NPRM been more explicit about the possibility of adopting the final rule, they would have submitted comments that differed in any material respect such that they were prejudiced by the alleged notice violation. Where, as here, any alleged violation of APA notice requirements "did not affect the outcome" and "did not prejudice the [plaintiffs], it would be senseless to vacate and remand for reconsideration." *PDK Laboratories Inc.* v. *DEA*, 362 F.3d 786, 799 (D.C. Cir. 2004).

3. The district court further erred by holding that the Secretary failed to provide a reasoned explanation for departing from her prior practice and from the 2003 NPRM in the final rule. This Court's holding in *Northeast* that the Secretary's pre-2004 practice was to exclude Part C days from the Medicare/SSI fraction does

not require the Court to undertake "more searching" or "heightened" review of the agency's decision in the 2004 final rule to change that practice and include Part C days. *FCC* v. *Fox Television Stations, Inc.*, 556 U.S. 502, 514-15 (2009).

When the agency promulgated its final rule in 2004, it considered the comments received and explained why it decided not to adopt its 2003 proposal to exclude Part C days from the Medicare/SSI fraction. See 69 Fed. Reg. at 49,099. The agency explained the basis for its decision when it stated that although there are differences between Medicare beneficiaries who enroll in Part C plans and those who do not, Part C enrollees remain "entitled to benefits under part A" in the relevant sense for determining whether they belong in the Medicare or Medicaid proxy of the DSH adjustment. *Id.* By agreeing with the commenters that opposed the proposal to exclude Part C days from the Medicare/SSI fraction because Part C enrollees "are just as much Medicare beneficiaries as those beneficiaries in the traditional fee-for-service program," the agency addressed the central question in determining congressional intent. *Id.* Because the agency addressed any comments that were "relevant to the agency's decision and which, if adopted, would require a change in an agency's proposed rule," it fully complied with APA requirements. *Home Box Office, Inc.* v. *FCC*, 567 F.2d 9, 35 n.58 (D.C. Cir. 1977).

4. This Court need not reach the issue of the proper remedy because the Secretary's 2004 rulemaking met APA notice-and-comment requirements. Even if the

district court's decision were correct on the merits, however, the court erred by vacating the portion of the 2004 final rule addressing the treatment of Part C days in the DSH calculation and prohibiting the Secretary from applying that interpretation to the calculation of plaintiffs' FY 2007 DSH adjustments.

First, if this Court holds that the Secretary complied with APA notice requirements in the 2003 NPRM, but determines that the agency did not provide a reasoned explanation in the 2004 final rule for its decision to include Part C days in the Medicare/SSI fraction, it should reverse the district court's remedial order. In determining whether vacatur of an agency rule is appropriate, this Court considers two factors: "(1) the seriousness of the . . . deficiencies of the action, that is, how likely it is the [agency] will be able to justify its decision on remand; and (2) the disruptive consequences of vacatur." See *Heartland Regional Med. Ctr.* v. *Sebelius*, 566 F.3d 193, 197 (D.C. Cir. 2009) (internal quotations omitted). If all that the agency is required to do on remand is provide a more thorough explanation for its decision to include Part C days in the Medicare/SSI fraction, these factors both weigh heavily in favor of a remand to the Secretary without vacatur. See *id.* at 197-98; *National Ass'n of Home Builders* v. *Defenders of Wildlife*, 551 U.S. 644, 657-58 (2007).

Second, even if this Court were to affirm the district court's decision on the merits in its entirety, it should modify the remedial order. The district court held that the portion of the 2004 final rule addressing the treatment of Part C days in the DSH

provision "is tantamount to the retroactive rulemaking that [this Court] held impermissible in *Northeast Hospital*." Op. 32, JA -. That holding is erroneous, and does not support the court's decision that the Secretary "cannot impose her new interpretations on the FY 2007 calculations challenged in this case." See *id.*

A 2004 final rule cannot be retroactive as applied to FY 2007. This Court's holding in *Northeast* regarding retroactivity applied solely to fiscal years prior to 2004. 657 F.3d at 16-17. By prohibiting the Secretary from including Part C days in the Medicare/SSI fraction in calculating plaintiffs' FY 2007 DSH adjustments because doing so would be "retroactive rulemaking," the district court erroneously rejected the Secretary's position that even if the 2004 rule were vacated, the Secretary would be free to adopt the same interpretation through case-by-case adjudication. See *SEC* v. *Chenery Corp.*, 332 U.S. 194 (1947); *Catholic Health Initiatives Iowa Corp.* v. *Sebelius*, -- F.3d --, 2013 WL 2476896 at *6-*7 (D.C. Cir. 2013). While the agency could no longer rely on the vacated rule in determining that the Part C days should be included in the Medicare/SSI fraction, there is no reason that the agency could not reach the same result by adjudication on remand. See *Heartland Regional Med. Ctr.* v. *Sebelius*, 415 F.3d 24, 29-30 (D.C. Cir. 2005).

STANDARD OF REVIEW

This Court reviews a district court's grant of summary judgment under a *de novo* standard. *Gilvin* v. *Fire*, 259 F.3d 749, 756 (D.C. Cir. 2001). In reviewing an agency's

interpretation of a statute that it administers, the Court applies the two-step framework established in *Chevron U.S.A. Inc.* v. *Natural Res. Def. Council, Inc.*, 467 U.S. 837, 842-43 (1984). Under this framework, a court must first ascertain "whether Congress has directly spoken to the precise question at issue." *Id.* at 842-43. If congressional intent is clear, "that is the end of the matter"; however, if the statute is "silent or ambiguous with respect to the specific issue," the agency's interpretation must be sustained as long as it is "based on a permissible construction" of the Act. *Id.* Moreover, the "Supreme Court has made clear that courts must give heightened deference to the Secretary's interpretation of a 'complex and highly technical regulatory program' such as Medicare." *Methodist Hosp.* v. *Shalala*, 38 F.3d 1225, 1229 (D.C. Cir. 1994) (quoting *Thomas Jefferson Univ.* v. *Shalala*, 512 U.S. 504, 512 (1994)).

Under APA standards, this Court will not set aside the Secretary's decision unless it is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," or "without observance of procedure required by law." 5 U.S.C. § 706(2)(A), (D). In applying this standard, the Court must "take 'due account' of 'the rule of prejudicial error.'" *First American Discount* v. *CFTC*, 222 F.3d 1008, 1015 (D.C. Cir. 2000) (quoting 5 U.S.C. § 706). "As incorporated into the APA, the harmless error rule requires the party asserting error to demonstrate prejudice from the error." *Id.* (internal quotations omitted).

In determining whether an agency has provided a reasoned explanation for its decision in a rulemaking, the Court applies the deferential "arbitrary and capricious" standard, pursuant to which "the scope of review" is "narrow"; a "court is not to substitute its judgment for that of the agency." *Motor Vehicles Mfrs. Ass'n* v. *State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). So long as the agency's construction of the statute is permissible and its "path may reasonably be discerned," the court must uphold the agency's interpretation under the APA. *Id.*

ARGUMENT

I. THE SECRETARY'S RULEMAKING SATISFIED APA PROCEDURAL REQUIREMENTS.

A. This Court Has Already Determined That The Secretary's Interpretation Of "Entitled To Benefits Under Part A" In The DSH Provision Is Consistent With The Plain Language Of The Medicare Statute.

Plaintiff hospitals in these cases challenged the Secretary's decision to include Medicare Part C days in the Medicare/SSI fraction of the DSH adjustment. Under the Secretary's interpretation, individuals who enroll in Medicare Part C plans remain entitled to benefits under part A, and their patient days thus are included in the Medicare/SSI fraction denominator. Although in most cases, the first question that a court must address is "whether Congress has directly spoken to the precise question at issue," (*Chevron*, 467 U.S. at 842), this Court has already decided that question in a previous case. In *Northeast*, this Court held that the plain language of the Medicare

statute did not foreclose Secretary's interpretation that an individual who meets the criteria for entitlement set forth in Section 426(a) or (b) is "entitled to benefits under Part A" within the meaning of the DSH provision, regardless of whether the individual has enrolled in an M+C plan under Medicare Part C or whether Medicare Part A has actually made payment for the days at issue. See *Northeast*, 657 F.3d at 6-13, 17-18. The Court determined that Congress "has left a statutory gap, and it is for the Secretary, not the court, to fill that gap." *Id.* at 13.

Although the Court in *Northeast* did not reach whether the Secretary's interpretation was reasonable at *Chevron* step 2, subsequent decisions of this Court confirm that the Secretary's interpretation is at the very least permissible. In *Catholic Health Initiatives*, this Court upheld the Secretary's interpretation of the same statutory language at issue here when it decided whether a Medicare beneficiary who has exhausted his coverage for a particular hospital stay remains "entitled to benefits under part A" within the meaning of the DSH provision. 2013 WL 2476896 at *5. As the Court explained, "[t]he basic arguments made by the parties in *Northeast Hospital* track those made here, and after a lengthy analysis * * * we found the statute ambiguous on this question." *Id.* The Court concluded that "[t]herefore, under *Chevron* * * * we of course defer to the Department's construction." *Id.* In doing so, this Court concluded that the Secretary's interpretation of "entitled to benefits under part A" is "the better one," though "it is not quite inevitable." *Id.* The combination

of *Catholic Health* and *Northeast* is dispositive of the statutory interpretation question here. See also *Hall* v. *Sebelius*, 667 F.3d 1293, 1296 (D.C. Cir. 2012); *Metropolitan Hosp.* v. *HHS*, 712 F.3d 248, 265-70 (6th Cir. 2013).

Here, the district court did not reach whether the Secretary's interpretation was reasonable at *Chevron* step 2 because it held that the Secretary had violated APA notice-and-comment requirements. Specifically, the court invalidated the Secretary's 2004 final rule on two procedural grounds: (1) failure to provide sufficient notice of the interpretation adopted in the final rule -- *i.e.*, that Part C patient days would be included in the Medicare/SSI fraction; and (2) failure to adequately explain a departure from the pre-2004 practice and the proposal in the NPRM to exclude Part C days from the Medicare/SSI fraction. Op. 20-31, JA -. As we demonstrate below, the Secretary's rulemaking fully complies with APA procedural requirements.

B. The Secretary Complied With The APA Notice Requirement In The 2003 NPRM.

1. The 2004 Final Rule Was A Logical Outgrowth Of The Proposed Rule.

Under the APA, an agency must provide notice of "either the terms or substance of the proposed rule or a description of the subjects and issues involved." 5 U.S.C. § 553(b)(3). Such notice "must be sufficient to fairly apprise interested parties of the issues involved, but it need not specify every precise proposal which

[the agency] may ultimately adopt as a rule." *Nuvio Corp.* v. *FCC*, 473 F.3d 302, 310 (D.C. Cir. 2007) (internal quotations omitted).

In the present case, the district court held that the agency's 2003 NPRM, which proposed to exclude Part C days from the Medicare/SSI fraction, did not give parties sufficient notice that the Secretary was considering adopting the contrary policy of including Part C days in the fraction. Op. 22-26, JA -. The court rejected the government's argument that the Secretary's interpretation in the 2004 final rule was a "logical outgrowth" of the proposal set forth in the NPRM that provided parties with the requisite notice under the APA. *Id.* In doing so, however, the district court overlooked crucial aspects of the rulemaking record that demonstrate that the interpretation adopted in the final rule was the logical and foreseeable alternative to the proposal in the NPRM. The court also misconstrued this Court's precedent applying the APA notice requirement.

a. As this Court has emphasized, an agency "is not required to adopt a final rule that is identical to the proposed rule." *Northeast Maryland Waste Disposal Auth.* v. *EPA*, 358 F.3d 936, 951 (D.C. Cir. 2004). Rather, "[a]gencies, are free – indeed, they are encouraged – to modify proposed rules as a result of the comments they receive." *Id.* An agency thus meets the APA notice requirement "as long as its final rule is a 'logical outgrowth' of the rule it originally proposed." *Id.* at 951-52 (quoting *First Am. Discount Corp.* v. *CFTC*, 222 F.3d at 1015). A final rule qualifies as a logical outgrowth

"if interested parties 'should have anticipated' that the change was possible, and thus reasonably should have filed their comments on the subject during the notice-and-comment period." *Id.* at 952 (quoting *City of Waukesha* v. *EPA*, 320 F.3d 228, 245 (D.C. Cir. 2003)).

Applying these principles, it is clear that the agency's 2004 final rule was a "logical outgrowth" of its 2003 proposal. In holding otherwise, the district court erroneously viewed the language of the 2003 NPRM as allowing for no other alternative to the proposed interpretation and failed to give sufficient weight to comments from hospitals, including some plaintiffs, which demonstrated their understanding of the "subjects and issues involved" in the rulemaking. See 5 U.S.C. 553(b)(3). The district court "beg[a]n[] with the proposition" that the Secretary's interpretation of the phrase "entitled to benefits under part A" in the Medicare/SSI fraction of the DSH provision as encompassing individuals enrolled in Part C, "'contradicts' and is a 'substantive departure' from 'her former practice of excluding M+C days from the Medicare fraction.'" Op. 20 (quoting *Northeast*, 657 F.3d at 17).[5]

[5] Although the district court properly used this Court's holding in *Northeast* as its starting point, we note that the court misunderstood the government's arguments regarding *Northeast* when it stated that the Secretary argued that "her current interpretation is entirely consistent with the past." Op. 2 n.2, JA -. In district court, the government acknowledged this Court's holding in *Northeast* that the agency's *practice* pre-2004 was to exclude Part C days from the Medicare/SSI fraction, but observed that the Court had not held that the agency had an authoritative *policy* or *legal*

But even in light of this Court's holding in *Northeast* that the 2004 final rule was a departure from the agency's prior practice with respect to Part C patient days, the 2003 NPRM satisfied APA notice requirements.

In the 2003 NPRM, the agency explained that "[w]e have received questions whether patients enrolled in an M+C Plan should be counted *in the Medicare fraction or the Medicaid fraction of the DSH patient percentage calculation*." 68 Fed. Reg. at 27, 208 (emphasis added). The agency thus presented the issue as a binary choice: either the Part C patient days would be included in the Medicare/SSI fraction or they would be excluded and instead included in the Medicaid fraction numerator if the Part C enrollee was eligible for Medicaid. Indeed, in the very next sentence, the agency noted that "[t]he question stems from whether M+C enrollees are entitled to benefits under Medicare Part A since M+C plans are administered through Medicare Part C." *Id.* The proposed rule thus clearly presented two – and only two – potential interpretations: Either M+C enrollees are "entitled to benefits under [Medicare] part A," and should be included in the Medicare/SSI fraction, or they are not so entitled, and they should be excluded.

Regardless of whether the agency's practice pre-2004 was to exclude Part C days from the Medicare/SSI fraction, its 2003 NPRM clearly reflected the fact that the

---

interpretation of "entitled to benefits under part A" that conflicts with the 2004 final rule.

agency was deciding which of two policy choices to make – to adopt an official policy to either include or exclude Part C days from the Medicare/SSI fraction. Providers therefore should have anticipated that either interpretation was possible and were on notice that they should submit comments to advocate for the interpretation that they preferred. See *Northeast Md. Waste Disposal*, 358 F.3d at 951-952. And, as set forth below, they did just that, as hospitals argued for both possible outcomes.

The district court concluded, however, that the 2003 NPRM "reads more like an afterthought of a clarification than a proposed rule susceptible of multiple interpretations." Op. 23, JA -. The court's characterization of the NPRM stems from the agency's statement that "we are proposing to *clarify* that once a beneficiary elects Medicare Part C, those patient days attributable to the beneficiary should not be included in the Medicare fraction of the DSH patient percentage." 68 Fed. Reg. at 27,208 (emphasis added). The court read the relevant sentence as if the agency had said "we are clarifying longstanding agency policy of excluding Part C days from the Medicare/SSI fraction." But that is not what the agency said or actually did in the NPRM. Rather, the agency made clear that it was "*proposing*" to exclude Part C days from the Medicare/SSI fraction, and that it was doing so in response to *questions* it had received about whether to include or exclude such days. 68 Fed. Reg. at 27,208 (emphasis added). Regardless of the agency's prior practice, the language of the rulemaking on its face shows that the agency was making a proposal to adopt one of

two possible interpretations with respect to Part C days, and was doing so in response to questions regarding its policy. *Id.*

As the agency explained, the question at issue was "whether M+C plan enrollees are entitled to benefits under Medicare Part A since M+C plans are administered through Medicare Part C." 68 Fed. Reg. at 27,208. The NPRM made clear that the agency previously did not have an authoritative statement of Medicare payment policy one way or the other. Indeed, the agency pointed out that "an individual is eligible to elect an M+C plan if *he or she is entitled to Medicare Part A* and enrolled in Part B," (*id.* (emphasis added)), which would lead to the conclusion that a Part C enrollee is "entitled to benefits under part A." But the agency further noted that "once a beneficiary has elected to join an M+C plan, that beneficiary's benefits are no longer administered under Part A." *Id.* The agency thus proposed to clarify whether an individual enrolled in Part C remains "entitled to benefits under part A" within the meaning of the DSH provision. *Id.* The agency's discussion of the two possible interpretations put providers on notice that they should submit comments if they agreed or disagreed with the agency's proposal. At the very least, the NPRM "gave interested parties a reasonable opportunity . . . to present relevant information on the central issues." *Nuvio Corp.*, 473 F.3d at 310 (internal quotations omitted).

The district court also erred by placing too great an emphasis on the fact that in the 2004 final rule, the Secretary "adopted the exact opposite interpretation from the

one she proposed." Op. 23, JA -. Apart from the proposed interpretation, the "exact opposite interpretation" was the only other *possible* interpretation that the Secretary could adopt. Thus, providers were on notice that if the Secretary decided *not* to adopt the proposal to exclude Part C days from the Medicare/SSI fraction, she would necessarily adopt the "exact opposite" policy of including Part C days. This does not equate to a lack of notice; to the contrary, it reflects the fact that an agency is free to change its proposed interpretation as a result of comments received in the rulemaking. See *Northeast Md. Waste Disposal*, 358 F.3d at 951. Here, since the only two potential outcomes were the proposed interpretation and what the district court termed its "exact opposite," a holding that the adoption of the opposite of the proposed rule violated the APA notice requirement would mean that HHS "could learn from the comments on its proposals only at the peril of subjecting itself to rulemaking without end." *Id.* (internal quotations omitted).

This Court's decision in *Northeast Md. Waste Disposal* is instructive. In that case, the Court held that the EPA had satisfied APA notice requirements because "[b]y announcing that it proposed to distinguish between refractory and nonrefractory units, EPA invited comments on both the pros and cons of that distinction." 358 F.3d at 952. As the Court explained, EPA "effectively served notice that, if persuaded that the latter outweighed the former, the distinction might not survive." *Id.* Here, by describing the two possible interpretations – *i.e.*, either Part C patient days would be

included in the Medicare/SSI fraction or they would not – and proposing to exclude such days, HHS similarly invited providers to submit comments on "both the pros and cons" of its proposal. As in *Northeast Md.*, providers thus had notice that if the cons outweighed the pros, HHS might not adopt its proposal, and, in that case, the only alternative was the interpretation actually adopted in the 2004 final rule.

For these reasons, the district court's reliance (op. 24, JA -) on this Court's decision in *Environmental Integrity Project* v. *EPA*, 425 F.3d 992 (D.C. Cir. 2005), is misplaced. In that case, the Court ruled that the EPA had violated APA notice requirements when, in the final rule, it "not only did not adopt the proposed interim rule but also adopted a 'reinterpretation' of the unamended text." 425 F.3d at 997. The Court emphasized that the EPA's proposed interim rule was consistent with the "bind[ing]" and "definitive interpretation[s]" that the agency had previously adopted in two administrative orders. *Id.* at 998. Because the EPA merely proposed to codify a previously-adopted binding interpretation by amending regulatory text, the court ruled that regulated parties lacked notice that this "*particular* aspect[] of its proposal [was] open for consideration." *Id.* In that context, the court held that the agency was not free to "repudiate its proposed interpretation and adopt its inverse." *Id.*

Contrary to the district court's holding, this case is not an analogous example of an agency using "'the rulemaking process to pull a surprise switcheroo on regulated entities.'" Op. 25, JA - (quoting *Environmental Integrity Project*, 425 F.3d at 996). Prior

to 2003, HHS did not have an authoritative statement of policy, much less a binding regulation, requiring the exclusion of patient days attributable to individuals enrolled in M+C plans from the Medicare/SSI fraction as proposed in the NPRM. To the contrary, the only prior binding agency legal interpretation relating to patient days of individuals enrolled in managed care plans was *consistent* with the 2004 final rule. From the inception of the Medicare program, as an alternative to the traditional fee-for-service system, Medicare beneficiaries have been able to enroll with a managed care organization, such as a health maintenance organization (HMO), which enters into a payment contract with Medicare to provide Medicare benefits to such enrollees. In a 1990 rulemaking, the Secretary considered it "appropriate to include the days associated with Medicare patients who receive care at a qualified HMO" in the Medicare/SSI fraction of the DSH calculation because "these beneficiaries are entitled to Part A benefits." 55 Fed. Reg. 35,990, 35,994 (Sept. 4, 1990).

Notably, although this Court held in *Northeast* that the Secretary's *practice* prior to 2004 was to exclude Part C days from the Medicare/SSI fraction and for this reason rejected the Secretary's reliance on the treatment of HMO days in the 1990 rulemaking as evidence of a longstanding policy, the Court did *not* hold that the Secretary had adopted a binding legal interpretation of the phrase "entitled to benefits under part A," either in adjudications or otherwise, that was contrary to the 2004 final rule. See *Northeast*, 657 F.3d at 16-17 (contrasting Secretary's "interpretation" in 2004

rulemaking with her former "practice" prior to rulemaking). Rather, the Court concluded that the rule against retroactive rulemaking applied in *Northeast* because "[p]rior to 2004, the regulation [42 C.F.R. 412.106(b)(2)] did not specify where M+C enrollees should be counted," and the agency had a practice of excluding the Part C days from the Medicare/SSI fraction. *Id.* at 14. The Court held that applying the amended regulation to fiscal years prior to its promulgation, during which the agency had a contrary practice, would violate the prohibition on retroactive rulemaking.

It is also significant that neither this Court in *Northeast* nor the district court below identified any agency policy of including patient days of Part C enrollees eligible for Medicaid in the Medicaid fraction numerator. As the agency explained in the 2003 NPRM, the question of whether Part C enrollees should be included in the Medicare or the Medicaid fraction "stems from whether M+C plan enrollees are entitled to benefits under Medicare Part A." 68 Fed. Reg. at 27,208. If they are not so entitled, then the patient days of the Part C enrollee "who is also eligible for Medicaid would be included in the numerator of the Medicaid fraction." *Id.* But the agency has never had an authoritative policy of including Part C days in the Medicaid fraction numerator. In *Northeast*, this Court did not cite any evidence that Part C days were included in the Medicaid fraction, nor was there such evidence in the record. Rather, the evidence was limited to the Secretary's prior practice of not including Part C days in the Medicare/SSI fraction. See 657 F.3d at 14-17. The fact that the agency did not

have a policy of including Part C days in the Medicaid fraction numerator further supports the agency's position that it never adopted a binding legal interpretation of "entitled to benefits under part A" contrary to the interpretation set forth in the 2004 final rule.

While the district court acknowledged that "a *de facto* practice is not quite as strong as the administrative opinions at issue in *Environmental Integrity Project*," it failed to recognize the additional, crucial difference between the proposed rule at issue in *Environmental Integrity Project* and the 2003 NPRM in the present case In *Environmental Integrity Project*, the EPA stated in its proposed rule that it was "proposing to remove" certain prefatory language in its regulation to "codify the understanding set forth in the *Pacificorp* and *Fort James* orders." 67 Fed. Reg. 58,561, 58,564 (Sept. 17, 2002). This Court ruled that a proposal to simply codify a current definitive legal interpretation does not put regulated parties on notice that the agency is considering a completely different interpretation. *Environmental Integrity Project*, 425 F.3d at 998. By contrast, in the 2003 NPRM, HHS referred to questions it had received regarding whether Part C days should be included in the Medicare/SSI fraction and described the only two possible interpretations with respect to the treatment of such days in the DSH calculation. 68 Fed. Reg. at 27,208. Nowhere did HHS refer to any prior agency policy with respect to Part C. In fact, in the NPRM, HHS described its proposed interpretation as a "proposed change," and acknowledged that "it appears

likely that there is some variation in how these days are currently being handled from one hospital and fiscal intermediary to the next." 68 Fed. Reg. at 27,416.

The agency's "proposed change" language makes sense even in light of this Court's holding in *Northeast*. As this Court recognized, prior to 2004, the applicable regulation did not specify whether Part C days should be included or excluded from the Medicare/SSI fraction. *Northeast*, 657 F.3d at 14. The 2003 NPRM put regulated parties on notice that the agency had decided to expressly address the issue in a binding regulation and invited their views on the proposal. Whatever proposal the agency ultimately adopted would constitute a change because it would, for the first time, be codified in binding agency regulations. In addition, the 2003 NPRM proposal was to include such days in the Medicaid fraction numerator for patients who were also "eligible for Medicaid." See 68 Fed. Reg. at 27,208. As noted, the agency had not previously done so as a matter of Medicare payment policy, nor was there any binding agency regulation requiring the agency or its contractors to do so. Thus, even if the agency had adopted the 2003 proposal, it would have changed agency practice, at least with respect to the Medicaid fraction. Unlike *Environmental Integrity Project*, this case is not an example of an agency simply proposing to codify a pre-existing policy where regulated parties might not anticipate the possibility of a departure from the proposal in the final rule.

b. The district court further erred by failing to recognize that the comments submitted by providers – *including some plaintiffs in this case* – demonstrate that the 2003 NPRM met the APA notice requirement. As set forth above, the agency received comments that opposed the proposal, recommending instead that Medicare Part C days "continue to be counted as Medicare days" in the DSH percentage because Medicare Part C enrollees are still beneficiaries entitled to part A benefits. ARR 327-28, 343, JA - (N. Shore Univ. Hosp. at Plainview); 356, 370-71, JA - (Ass'n of Am. Med. Colleges); 403, 412-13, JA - (NYU Med. Ctr.); 451-52, 466, JA - (Greater NY Hosp. Ass'n); 555-56, 571, JA - (Franklin Hosp.); 576, 591, JA - (N. Shore Univ. Hosp. at Syosset). These commenters included North Shore University Hospital and Franklin Hospital, part of the North Shore Long Island Jewish Health System and plaintiffs in this case. RA1, JA -. The commenters also included the Association of American Medical Colleges, which noted that it represents "approximately 400 major teaching hospitals and health systems; all 126 accredited U.S. medical schools; 96 professional and academic societies; and the nation's medical students and residents," and the Greater New York Hospital Association, which stated that its comments were on behalf of "more than 100" member hospitals. ARR 356, 451, JA -.

In contrast, a few commenters agreed with the agency's proposal to exclude the Part C days from the Medicare/SSI fraction. See ARR 140, 144, 145, 147-49, JA - (Sw. Consulting Assoc.); 389-90, JA - (Mercy Health Sys.). And while it did not

address the substantive merits of the proposal, plaintiff Allina Hospitals and Clinics submitted comments detailing its "operational concerns" about the agency's proposal "to include all patients with M+C coverage in *the Medicaid percentage of the DSH determination rather than the Medicare percentage*." ARR 449, JA - (emphasis added).

These comments demonstrate that providers plainly understood the two possible outcomes of the rulemaking. See *Appalachian Power Co.* v. *EPA*, 135 F.3d 791, 816 (D.C. Cir. 1998) ("[c]ommenters clearly understood that these [interpretations] were under consideration, as the agency received comments on them from several sources"); *Nuvio Corp.*, 473 F.3d at 310 (citing comments received as evidence that NPRM "gave interested parties a reasonable opportunity . . . to present relevant information on the central issues") (internal quotations omitted). Because commenters anticipated the only two potential outcomes of the proposed rule, the final rule was a logical outgrowth of the NPRM.

Although the district court acknowledged that "some of the commenters understood the import of the 2003 NPRM and either supported or opposed it, and some of the [plaintiff] Hospitals even argued in favor of the interpretation they now challenge," it erroneously rejected the Secretary's reliance on these comments because, in its view, "taken as a whole, they reflect confusion and misunderstanding." Op. 25, JA -. The court cited plaintiff North Shore University Hospital's comments – which opposed the very interpretation plaintiff hospitals now advocate – to support this

point. *Id.* But North Shore's comment that the proposal "would remove M+C days from the Medicare day count" simply reflects that the agency was clarifying its policy in response to "questions" whether patients enrolled in Part C should be included in the Medicare/SSI fraction. 68 Fed. Reg. at 27,208, 27,416. Indeed, it was the receipt of such "questions" that caused the agency to issue a proposed rule in the first instance. See *id.*

This Court's holding in *Northeast* that the agency had a practice of excluding M+C days from the Medicare/SSI fraction prior to the 2004 final rule does not change the analysis. The NPRM on its face demonstrates that the agency recognized that there was confusion among providers and intermediaries about the agency's practice in the absence of an official policy or binding regulation. The district court missed the crucial point that the comments cited by the Secretary demonstrate that providers understood the two possible outcomes of the rulemaking and recognized that they needed to submit comments if they had views about which interpretation the Secretary should adopt.

2. Even Assuming *Arguendo* That The 2003 NPRM Did Not Comply With APA Notice Requirements, Any Violation Would Be Harmless Error.

The district court further erred by rejecting the Secretary's argument that even assuming *arguendo* that the agency violated APA notice requirements, any such violation would be harmless error. Under the APA, plaintiffs "must demonstrate that

the agency's violation of the APA's notice and comment procedures has resulted in 'prejudice.'" *American Coke & Coal Chem. Inst.* v. *EPA*, 452 F.3d 930, 939 (D.C. Cir. 2006) (quoting 5 U.S.C. § 706(2)); see *First Am. Discount Corp.*, 222 F.3d at 1015 (Court need not resolve whether final rule was "logical outgrowth" of proposed rule because agency's "failure to re-notice the guarantee option was at best harmless").

First, the court applied the wrong standard for determining whether any procedural violation was harmless. See op. 26, JA -. The court held that the "confusion over the Secretary's interpretation of the DSH calculation" and the "large amount of money at stake" satisfy the "'not . . . particularly robust showing of prejudice' courts require in these cases." *Id.* (quoting *Chamber of Commerce* v. *SEC*, 443 F.3d 890, 904 (D.C. Cir. 2006)). But as this Court made clear in the case quoted by the district court, this "not . . . particularly robust showing of prejudice" standard applies only when there has been an "'utter failure to comply with notice and comment'" requirements by the agency. *Chamber of Commerce*, 443 F.3d at 904 (quoting *Sugar Cane Growers Co-op of Fla.* v. *Veneman*, 289 F.3d 89, 96 (D.C. Cir. 2002)). Indeed, in *Chamber of Commerce*, the Court noted that "the instant case does not involve the outright dodge of APA procedures that led the court to permit a limited showing of prejudice." *Id.* The Court therefore did not apply the lower standard applicable to such cases – *i.e.*, prejudice is shown when there is "*any uncertainty at all* as to the effect" of the agency's complete failure to follow APA notice-and-comment procedures. *Id.*

(emphasis added) (internal quotations omitted). Rather, the court determined that the petitioner had shown *"enough* [un]certainty whether [its] comments would have had some effect if they had been considered * * * to show prejudice." *Id.* (emphasis added) (internal quotations omitted). The Court's extended discussion in *Chamber of Commerce* of petitioner's showing that it "has been prejudiced by the Commission's reliance on materials not in, nor merely 'supplementary' to, the rulemaking record" demonstrates that the applicable standard mandates more than the "limited showing of prejudice" that the district court found sufficient here. *Id.* at 904-06.

The present case does not involve an "utter failure" to comply with APA notice-and-comment requirements. To the contrary, the agency promulgated a proposed rule in which it solicited comments from providers, and received numerous comments on its proposals involving the DSH provision, including the proposal to exclude Part C days from the Medicare/SSI fraction. Plaintiffs thus cannot show that "had proper notice been provided, they would have submitted additional, different comments that could have invalidated the [agency's] rationale." *City of Waukesha*, 320 F.3d at 246. Indeed, two plaintiffs actually submitted comments opposing the very interpretation that they advocate in this case, and another plaintiff detailed its "operational concerns" about the proposal. See *supra* pp. 35-36. Plaintiffs have not shown – nor could they – that had the NPRM been more explicit about the possibility of adopting the final rule, they would have submitted comments that differed in any

material respect such that they were prejudiced by the alleged notice violation found by the district court. Where, as here, any failure to provide adequate notice "did not affect the outcome" and "did not prejudice the [plaintiffs], it would be senseless to vacate and remand for reconsideration." See *PDK Laboratories Inc.* v. *DEA*, 362 F.3d 786, 799 (D.C. Cir. 2004); *First Am. Discount*, 222 F.3d at 1015.

Thus, even if this Court were to hold that the 2003 NPRM did not meet APA notice requirements, it should reverse the district court's judgment on the ground that any such violation was harmless error.

C. The Secretary Provided A Reasoned Explanation For Her Decision To Include Part C Patient Days In The Medicare/SSI Fraction.

1. The district court also held, in the alternative, that in the 2004 final rule, the Secretary failed to provide a sufficient explanation for her departure from her established pre-2004 practice of not including Part C days in the Medicare/SSI fraction. Op. 28-31, JA -. At the outset, this Court's holding that the Secretary's construction of the DSH provision in 2004 was a departure from the agency's past practice with respect to Part C days does not require "more searching" or "heightened" review of the agency's action under the APA. *FCC* v. *Fox Television Stations, Inc.*, 556 U.S. 502, 514-15 (2009). As demonstrated, in the 2004 final rule, the agency did not change a past authoritative statement of Medicare payment policy with respect to Part C days. In any event, even if it had, an "agency's interpretation of a

statute is entitled to no less deference * * * simply because it has changed over time." *National Home Equity Mortgage Ass'n* v. *Office of Thrift Supervision*, 373 F.3d 1355, 1360 (D.C. Cir. 2004). An agency's new interpretation is not arbitrary and capricious so long as it "provide[s] a reasoned analysis," in the rulemaking. See *id.* As the Supreme Court emphasized, the APA "makes no distinction" with respect to the standard of review between "initial agency action and subsequent agency action undoing or revising that action." *Fox Television*, 556 U.S. at 515.

When HHS promulgated its final rule in 2004, it considered the comments received and discussed why it did not adopt its 2003 proposal to exclude Part C days from the Medicare/SSI fraction. See 69 Fed. Reg. at 49,099. The agency acknowledged that it had proposed to exclude Part C days from the Medicare/SSI fraction and to include them in the Medicaid fraction numerator if the Part C enrollee was also eligible for Medicaid. *Id.* HHS noted that, in response, it had received comments that appreciated the agency's attention to the issue because "there has been insufficient guidance on how to handle these days in the DSH calculation." *Id.* The agency further noted that "several commenters disagreed" with the proposal and "pointed out that these patients [Part C enrollees] are just as much Medicare beneficiaries as those beneficiaries in the traditional fee-for-service program." *Id.* While the agency stated that there were differences between these types of beneficiaries, it ultimately agreed with the commenters that opposed the proposed

rule because "once Medicare beneficiaries elect Medicare Part C coverage, they are still, in some sense, entitled to benefits under Medicare Part A." *Id.* The agency therefore determined that it would "not adopt[] as final our proposal stated in the May 19, 2003 proposed rule to include the days associated with M+C beneficiaries in the Medicaid fraction." *Id.* The agency explained that it was instead "adopting a policy" of including the Part C days in the Medicare fraction and was "revising our regulations at § 412.106(b)(2)(i) to include the days associated with M+C beneficiaries in the Medicare fraction of the DSH calculation." *Id.*

The agency thus addressed relevant comments and explained the rationale of its decision: Part C enrollees remain "entitled to benefits under part A" in the relevant sense for determining whether they belong in the Medicare or Medicaid proxy of the DSH adjustment. The district court found it particularly significant, however, that the Secretary did not acknowledge her pre-2004 practice of not including Part C days in the Medicare/SSI fraction. Op. 28, JA -. But while the Supreme Court has opined that "the requirement that an agency provide reasoned explanation for its action would ordinarily demand that it display awareness that it *is* changing position," the Court did not hold that such an acknowledgment is always necessary. See *Fox Television*, 556 U.S. at 515. To the contrary, the Court explained that an "agency may not, for example, depart from a prior policy *sub silentio* or simply disregard rules that are still on the books." *Id.* Neither of these concerns is present here. As this Court

recognized, at the time of the 2003 NPRM, the agency's applicable regulation did not specify how Part C days should be treated for DSH purposes. *Northeast*, 657 F.3d at 14. Nor was there any authoritative agency legal interpretation or Medicare payment policy providing that Part C days should be excluded from the Medicare/SSI fraction that required discussion. The agency's NPRM and final 2004 rule made clear the two potential ways its regulation could be amended to specifically address treatment of Part C days.

The district court further faulted the Secretary for failing to discuss subjects raised by comments, including "the need to reconcile Congressional intent regarding the DSH fraction and the M+C program, which were enacted years apart, and the financial impact of counting Part C days in the Medicaid fraction." Op. 30, JA -. But the Secretary's explanation met applicable standards because it did address the central interpretive issue: whether Part C enrollees remain "entitled to benefits under part A" within the meaning of the DSH provision. Indeed, the specific comments to which the Secretary responded were the most relevant to the question before the agency in the rulemaking – how best to interpret "entitled to benefits under part A" in the DSH provision. This is also the key question in determining congressional intent with respect to the treatment of Part C days in the DSH fraction, and its resolution

does address how the M+C program affects the calculation of the DSH adjustment.[6] Cf. op. 30.

Indeed, by agreeing with comments that opposed the proposal to exclude Part C days from the Medicare/SSI fraction because Part C enrollees "are just as much Medicare beneficiaries as those beneficiaries in the traditional fee-for-service program," and stating that in the relevant sense, Part C enrollees remain "entitled to benefits under Medicare Part A," the agency adequately explained the basis for its determination that Part C days should be included in the Medicare/SSI fraction. See 69 Fed. Reg. at 49,099. When Congress enacted the DSH provision, it intended that the Medicare/SSI fraction serve as a proxy for the percentage of low-income *Medicare* patients, while the Medicaid fraction was intended to serve as a proxy for low-income *non-Medicare* patients. See *Catholic Health Initiatives*, 2013 WL 2476896 at *2. When it created Part C over a decade later, Congress provided that to enroll in Part C, a

[6] The district court also overlooked the fact that in the 2003 NPRM, the agency had already explained that it did "not have data readily available to assess" the financial impact of its proposal with respect to Part C days, but that "it appears likely that there is some variation in how these days are currently being handled by hospitals and fiscal intermediaries," and it "believe[d] there should not be a major impact associated with this proposed change." 68 Fed. Reg. at 27,416. Moreover, this is not a case where the financial impact is readily apparent; rather, it depends on various factors such as the percentage of a hospital's patients enrolled in Part C, and the percentage of Part C enrollees who are entitled to SSI and/or eligible for Medicaid. See *Catholic Health Initiatives*, 2013 WL 2476896 at *2 (noting parties' dispute regarding financial impact and finding that "in at least some cases" including dual-eligible exhausted days in Medicaid fraction would benefit hospitals).

beneficiary must be "entitled to benefits under [Medicare] part A" – the same wording that Congress used in the DSH provision. 42 U.S.C. § 1395w-21(a)(3)(A); 42 U.S.C. § 1395ww(d)(5)(F)(vi)(I). The comment from the Association of American Medical Colleges that individuals enrolled in Part C are "just as much Medicare beneficiaries," as Medicare beneficiaries who have not enrolled in Part C (see ARR 371, JA -), and the Secretary's agreement with this comment thus reflect that individuals enrolled in Part C are a subset of individuals "entitled to benefits under part A," and accordingly should be included in the *Medicare* proxy. See 69 Fed. Reg. at 49,099; 42 U.S.C. § 1395w-21(a)(3)(A).

In short, the agency's explanation was sufficient under the deferential "arbitrary and capricious" standard, pursuant to which "the scope of review" is "narrow," and "a court is not to substitute its judgment for that of the agency." *Motor Vehicles Mfrs. Ass'n* v. *State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). So long as the agency's construction of the statute is permissible (which it is, under this Court's analysis in *Northeast* and *Catholic Health*) and its "path may reasonably be discerned," the court must uphold the agency's interpretation under the APA. *Id.* Here, as demonstrated above, the agency's explanation is "tolerably terse * * * especially in light of the particular deference" that this Court "afford[s] the Secretary given the tremendous complexity of the Medicare statute." *Appalachian Regional Healthcare, Inc.* v. *Shalala*, 131

F.3d 1050, 1054 (D.C. Cir. 1997) (citing *Methodist Hosp.* v. *Shalala*, 38 F.3d 1225, 1229 (D.C. Cir. 1994)).

2. Even if this Court were to disagree and find that the agency's explanation was not adequate, it should still reverse the district court's remedial order. The district court's holding that the agency failed to provide a reasoned explanation is not an alternative grounds for ordering vacatur of the relevant portion of the 2004 final rule. To the contrary, in determining whether vacatur is appropriate, this Court considers two factors: "(1) the seriousness of the . . . deficiencies of the action, that is, how likely it is the [agency] will be able to justify its decision on remand; and (2) the disruptive consequences of vacatur." See *Heartland Regional Med. Ctr.* v. *Sebelius*, 566 F.3d 193, 197 (D.C. Cir. 2009) (internal quotations omitted). If the agency's only procedural error in the rulemaking was a failure to provide an adequate explanation for its decision, then these factors would weigh heavily in favor of a remand without vacatur. See *id.* at 197-98 ("[w]hen an agency may be able readily to cure a defect in its explanation of a decision, the first factor * * * counsels remand without vacatur"; vacating rule that was in effect for six years would have highly disruptive effect on HHS); *National Ass'n of Home Builders* v. *Defenders of Wildlife*, 551 U.S. 644, 657-58 (2007) ("if the EPA's action was arbitrary and capricious * * * the proper course would have been to remand to the Agency for clarification of its reasons"). This principle applies with particular force, where, as here, this Court has (1) already

determined that the Medicare statute does not foreclose the Secretary's interpretation at *Chevron* step 1 (*Northeast*, 657 F.3d at 6-13), and (2) in a closely related context involving the Secretary's interpretation of the same statutory language, already held that the Secretary's "interpretation is the better one," though "not quite inevitable." *Catholic Health Initiatives*, 2013 WL 2476896 at *5.

II. THIS COURT SHOULD VACATE THE DISTRICT COURT'S REMEDIAL ORDER.

Because the Secretary complied with APA procedural requirements, this Court need not reach the issue of the proper remedy. Moreover, as we have shown, even if this Court holds that HHS did not adequately explain its decision in the 2004 final rule to include Part C days in the Medicare/SSI fraction, the proper remedy is a remand to the agency without vacatur.

Even if this Court were to affirm the district court's holdings on the merits in full, however, it should reverse the district court's remedial order, which not only vacates a portion of the 2004 final rule, but also requires the agency to exclude Part C days from the Medicare/SSI fraction in determining plaintiff hospitals' DSH adjustments for FY 2007. Op. 32, JA -. Here, the district court's remedial order went further than simply ordering vacatur. The court also held that the "portion of the 2004 Final Rule * * * that announced the Secretary's interpretation of the Medicare [DSH] Fraction, as codified in 2007 at 42 C.F.R. § 412.106(b)(2) and as further

modified in 2010, is tantamount to the retroactive rulemaking that the D.C. Circuit held impermissible in *Northeast Hospital*." Op. 32. The court added that "[b]ecause the Secretary did not validly change her interpretation of the DSH calculation prior to FY 2007, and because there is no statute that authorizes the Secretary to promulgate retroactive rules for DSH calculations * * * the Secretary cannot impose her new interpretation on the FY 2007 calculations challenged in this case." *Id.* (internal quotations and citation omitted).

A 2004 final rule cannot be retroactive as applied to FY 2007, however. This Court's holding in *Northeast* expressly applied solely to fiscal years prior to 2004. 657 F.3d at 16-17. By ruling that the Secretary could not include Part C days in the Medicare/SSI fraction in calculating plaintiffs' FY 2007 DSH adjustments because doing so would be "retroactive rulemaking," the district court erroneously rejected the agency's position that even if the 2004 rule were vacated, the Secretary would be free to adopt the same interpretation through case-by-case adjudication. See *SEC* v. *Chenery Corp.*, 332 U.S. 194, 201-04 (1947); *Catholic Health Initiatives*, 2013 WL 2476896 at *6-*7 (D.C. Cir. 2013).

The district court's remedial order – vacating the rule and prohibiting the Secretary from applying the interpretation set forth in the 2004 final rule to plaintiffs' DSH adjustments for the fiscal year at issue – improperly assumes that, to depart from the agency practice that the D.C. Circuit found existed in *Northeast* prior to 2004,

the agency would be required to engage in notice-and-comment rulemaking. But while the Secretary chose to address the treatment of Part C days for purposes of the DSH calculation in notice-and-comment rulemaking, she did not need to do so in order to effect a change from prior practice. It should therefore follow that even if the notice-and-comment rule is vacated, the agency should be free to reach the same result through case-by-case adjudication. While the agency would no longer be able to rely on the regulation in determining that the Part C days should be included in the Medicare/SSI fraction, there is no reason that the agency could not reach the same result by adjudication on remand. See *Heartland Regional Med. Ctr.* v. *Sebelius*, 415 F.3d 24, 29-30 (D.C. Cir. 2005).

Indeed, as this Court recently held, HHS may establish a new policy or practice in an adjudication, which "is by its nature retroactive" unless plaintiffs can show, *inter alia*, that "'deny[ing] retroactive effect' * * * is 'necessary . . . to protect the settled expectations of those who had relied on the preexisting rule.'" *Catholic Health Initiatives*, 2013 WL 2476896 at *6 (quoting *Williams Natural Gas Co.* v. *FERC*, 3 F.3d 1544, 1554 (D.C. Cir. 1993)). In the present case, regardless of whether the 2003 NPRM gave providers adequate notice, plaintiffs cannot claim that they relied on any contrary "practice" of the agency from 2004 forward. The problem the court identified in *Northeast* was that the agency had a practice of excluding Part C days from the Medicare/SSI fraction prior to 2004, and thus, the 2004 final rule "attached

new legal consequences to hospitals' treatment of low-income patients" during fiscal years 1999-2002. 657 F.3d at 17. The agency has since altered its practice in accordance with the 2004 final rule, however, and thus, the Secretary should be able to decide how to treat Part C days in the Medicare/SSI fraction plaintiffs' FY 2007 DSH calculations by adjudication on remand.

CONCLUSION

For the foregoing reasons, the district court's judgment should be reversed.

Respectfully submitted,

STUART F. DELERY
Acting Assistant Attorney General
RONALD C. MACHEN JR.
United States Attorney
ANTHONY J. STEINMEYER
(202)-514-3388
STEPHANIE R. MARCUS
(202) 514-1633
Attorneys, Appellate Staff
Civil Division, Room 7642
Department of Justice
950 Pennsylvania Ave., N.W.
Washington, D.C. 20530

July 1, 2013

CERTIFICATE OF COMPLIANCE

Pursuant to Fed. R. App. P. 32(a)(7)(c), I hereby certify that the foregoing brief complies with the type-volume limitation in Fed. R. App. P. 32(a)(7)(B), the typeface requirements of Fed. R. App. P. 32(a)(5), and the type style requirements of Fed. R. App. 32(a)(6). The word processing program (Microsoft Word 2010) used to prepare the brief reports that the brief is 12,618 words long. The brief has been prepared in a proportionally spaced typeface using Microsoft Word 2010 with Garamond, 14 point font.

/s/ Stephanie R. Marcus
Stephanie R. Marcus

CERTIFICATE OF SERVICE

I hereby certify that on this 1st day of July, 2013, I electronically filed the foregoing Brief For Appellant Kathleen Sebelius with the Clerk of the Court for the United States Court of Appeals for the D.C. Circuit by using the appellate CM/ECF system. I also certify that I will cause an original and five paper copies of the brief to be hand-delivered to the Court within two business days.

I further certify that on this 1st day of July, 2013, I served the foregoing Brief For Appellant Kathleen Sebelius on the following counsel by electronic service via the CM/ECF system:

Stephanie A. Webster
J. Harold Richards
Hyland Hunt
Akin Gump Strauss Hauer & Feld LLP
1333 New Hampshire Ave., NW
Washington, D.C. 20036
swebster@akingump.com
jrichards@akingump.com
hhunt@akingump.com

Dennis M. Barry
King & Spalding LLP
1700 Pennsylvania Ave., NW
Suite 200
Washington, D.C. 20006
dbarry@kslaw.com

/s/ Stephanie R. Marcus
Stephanie R. Marcus